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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/558,576	04/26/00	WHITSETT M.D. J	CHMC7.001CP1

020995 HM22/1010
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EXAMINER	
CROUCH,D	
ART UNIT	**PAPER NUMBER**
1632	4

DATE MAILED: 10/10/00

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/558,576	Whitsett
Examiner	**Group Art Unit**
Deborah Crouch	1632

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one (1)* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-28* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-28* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 21, drawn to a mammal with and SP-D null phenotype and methods of identifying pharmaceutical agents, classified in class 800, subclass 14 and subclass 3.

II. Claims 4-6 and 25-28, drawn to methods of treatment comprising introducing SP-D protein, classified in class 514, subclass 12.

III. Claims 4,5,7-9,13-15 and 25-27, drawn to method of treatment comprising introducing a vector expressing SP-D protein and a vector expressing SP-D protein, classified in class 514, subclass 44 and class 435, subclass 320.1.

IV. Claim 10, drawn to a pharmaceutical composition comprising SP-D protein, classified in class 514, subclass 12.

V. Claims 11 and 12, drawn to a biologically active agent that up regulates expression of SP-D, classified in class 514, subclass 1+

VI. Claim 16, drawn to a biologically active agent that interacts with SP-D, classified in class 514, subclass 1+.

VII. Claims 17 and 18, drawn to a method for diagnosing susceptibility to pulmonary disease by identification of a mutation in the SP-D gene by PCR analysis, classified in class 435, subclass 6.

VIII. Claims 17 and 19, drawn to a method for diagnosing susceptibility to pulmonary disease by identification of a mutation in the SP-D gene by hybridization analysis, classified in class 435, subclass 6.

IX. Claims 17 and 20, drawn to a method for diagnosing susceptibility to pulmonary disease by identification of a mutation in the SP-D gene by ELISA, classified in class 435, subclass 7.1.

X. Claims 22-24, drawn to a method of purifying SP-D antibodies, classified in class 530, subclass 413.

The inventions are distinct, each from the other because:

Inventions I and II are mutually exclusive and independent. Invention I is to a mammal with an SP-D null phenotype. Invention II is to a method treatment comprising introducing SP-D protein. The protocols for producing the mammal of invention I and the protocols for the method of treatment in invention II are materially different and separate. Neither invention I is required for the implementation of invention II, or vice-versa.

Inventions I and III are mutually exclusive and independent. Invention I is to a mammal with an SP-D null phenotype. Invention II is to a method treatment comprising introducing a vector expressing SP-D protein. The protocols for producing the mammal of invention I and the protocols for the method of treatment in invention III are materially different and separate. Neither invention I is required for the implementation of invention III, or vice-versa.

Inventions I and IV are mutually exclusive and independent. Invention I is to a mammal with an SP-D null phenotype. Invention IV is to a pharmaceutical composition comprising SP-D protein. The protocols for producing the mammal of invention I and the protocols for making invention IV are materially different and separate. Neither invention I is required for the implementation of invention IV, or vice-versa.

Inventions I and V are mutually exclusive and independent products. Invention I is not needed for the implementation of invention V, and vice versa.

Inventions I and VI are mutually exclusive and independent products. Invention I is not needed for the implementation of invention VI, and vice versa.

Inventions I and VII are mutually exclusive and independent. The methods of making the mammal of invention I are materially different and separate from the methods for invention VII, a method of diagnosis by PCR. Neither invention I nor invention VII are required for the implementation of the other method.

Inventions I and VIII are mutually exclusive and independent. The methods of making the mammal of invention I are materially different and separate from the methods for invention VIII, a method

of diagnosis by hybridization. Neither invention I nor invention VII are required for the implementation of the other method.

Inventions I and IX are mutually exclusive and independent. The methods of making the mammal of invention I are materially different and separate from the methods for invention IX, a method of diagnosis by ELISA. Neither invention I nor invention IX are required for the implementation of the other method.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the SP-D null mammal can be used to assay for treatment protocols.

Inventions II and III are mutually exclusive and independent method of treatment. Invention II requires the active agent to be SP-D protein delivered directly. Invention III requires the active agent SP-D protein be delivered by the administration of a vector expression SP-D protein. The protocols for treatment are materially different and separate. Further, the method of treatment in invention I is not required for the method of treatment in invention III.

Inventions II and IV are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition can be used to produce antibodies in vivo.

Inventions II and V are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the biologically active agent composition can be used to produce antibodies in vivo.

Inventions II and VI are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the biologically active agent composition can be used to produce antibodies in vivo.

Invention II and any one of inventions VII, VIII or IX are mutually exclusive and independent. Invention II is to a method of treatment comprising introducing SP-D protein. Inventions VII, VIII and IX are to methods for in vitro methods of diagnosis. The protocols for the method for treatment in invention II, and the methods of diagnosis of inventions VII, VIII and IX are materially different and separate. In addition, the method of treatment in invention II is not needed for the implementation of any of the methods of diagnosis of inventions VII, VIII or IX.

Invention II and invention X are mutually exclusive and independent. Invention II is to a method of treatment comprising introducing SP-D protein. Inventions X is to a method for purifying SP-D protein antibodies. The protocols for the method for treatment in invention II, and the method for purifying of inventions X are materially different and separate. In addition, the method of treatment in invention II is not needed for the implementation of the method of purification of inventions X.

Invention III and IV are mutually exclusive and independent. Invention III is to a method of treatment comprising administering a vector expression SP-D protein. Invention IV is to a pharmaceutical composition comprising SP-D protein. The method of invention III does not require the pharmaceutical composition of invention IV, and vice versa.

Invention III and V are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the biologically active agent composition can be used to produce antibodies in vivo.

Invention III and VI are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the biologically active agent composition can be used to produce antibodies in vivo.

Invention III and any one of inventions VII, VIII or IX are mutually exclusive and independent. Invention III is to a method of treatment comprising administering a vector expression SP-D protein. Inventions VII, VIII and IX are to methods for in vitro methods of diagnosis. The protocols for the method for treatment in invention III, and the methods of diagnosis of inventions VII, VIII and IX are materially different and separate. In addition, the method of treatment in invention III is not needed for the implementation of any of the methods of diagnosis of inventions VII, VIII or IX.

Invention III and invention X are mutually exclusive and independent. Invention III is to a method of treatment comprising administering a vector expression SP-D protein. Inventions X is to a method for purifying SP-D protein antibodies. The protocols for the method for treatment in invention II, and the method for purifying of inventions X are materially different and separate. In addition, the method of treatment in invention II is not needed for the implementation of the method of purification of inventions X.

Inventions IV and V are mutually exclusive and independent products. Invention IV is to a pharmaceutical composition. Invention V is to an agent that up regulates expression of SP-D protein. The products are unrelated in operation, and as such are independent products. Further, neither the product of invention IV is required for the implementation of the production of invention V, and vice versa.

Inventions IV and VI are mutually exclusive and independent products. Invention IV is to a pharmaceutical composition. Invention VI is to an agent that interacts with SP-D protein. The products are unrelated in operation, and as such are independent products. Further, neither the product of invention IV is required for the implementation of the production of invention VI, and vice versa.

Invention IV and any one of inventions VII, VIII and IX are mutually exclusive and independent. Invention IV is to a pharmaceutical composition. Inventions VII, VIII and IX are to methods for in vitro methods of diagnosis. Invention IV is not needed for the implementation of any of inventions VII, VIII or IX, and vice versa.

Inventions IV and X are mutually exclusive and independent. Invention IV is to a pharmaceutical composition. Invention X is to a method for purifying SP-D antibody. The pharmaceutical composition of invention IV is not required for the method of purifying SP-D antibodies of invention X, and vice versa.

Inventions V and VI are mutually exclusive and independent products. The agent of invention V acts to up regulate expression of SP-D. The agent of invention VI acts to interact with SP-D protein. Thus the agents of materially different and separate operation. Further, the agent of invention V and the agent of invention VI are not required for each other's action.

Invention V and any one of inventions VII, VIII and IX are mutually exclusive and independent. Invention V is to an agent that up regulates expression of SP-D protein. Inventions VII, VIII and IX are to methods for in vitro methods of diagnosis. Invention V is not needed for the implementation of any of inventions VII, VIII or IX, and vice versa.

Inventions V and X are mutually exclusive and independent. Invention V is to an agent that up regulates expression of SP-D protein. Invention X is to a method for purifying SP-D antibody. The agent of invention V is not required for the method of purifying SP-D antibodies of invention X, and vice versa.

Invention VI and any one of inventions VII, VIII and IX are mutually exclusive and independent. Invention VI is to an agent that up interacts with of SP-D protein. Inventions VII, VIII and IX are to methods for in vitro methods of diagnosis. Invention VI is not needed for the implementation of any of inventions VII, VIII or IX, and vice versa.

Inventions VI and X are mutually exclusive and independent. Invention V is to an agent that interacts with SP-D protein. Invention X is to a method for purifying SP-D antibody. The agent of invention VI is not required for the method of purifying SP-D antibodies of invention X, and vice versa.

Inventions VII and invention VIII are mutually exclusive and independent methods of diagnosis. The method of invention VII is to a PCR method of analysis of DNA. The method of invention VIII is to the detection of mutations by hybridization analysis. The protocols for each method are materially different and separate. Further, the method of invention VII is not needed for the method of invention VIII, and vice versa.

Inventions VII and IX are mutually exclusive and independent methods of diagnosis. The method of invention VII is to a PCR method of analysis of DNA. The method of invention IX is to the detection of mutations by ELISA. The protocols for each method are materially different and separate. Further, the method of invention VII is not needed for the method of invention IX, and vice versa.

Inventions VII and X are mutually exclusive and independent. Invention VII is to a method of diagnosis using PCR. Invention X is to a method for purifying SP-D antibody. The method of invention VII is not required for the method of purifying SP-D antibodies of invention X, and vice versa.

Inventions VIII and IX are mutually exclusive and independent methods of diagnosis. The method of invention VIII is to a method of DNA analysis by hybridization. The method of invention IX is to the detection of mutations by ELISA. The protocols for each method are materially different and separate. Further, the method of invention VIII is not needed for the method of invention IX, and vice versa.

Inventions VIII and X are mutually exclusive and independent. The method of invention VIII is to a method of DNA analysis by hybridization. Invention X is to a method for purifying SP-D antibody. The method of invention VIII is not required for the method of purifying SP-D antibodies of invention X, and vice versa.

Inventions IX and X are mutually exclusive and independent. The method of invention IX is to the detection of mutations by ELISA. Invention X is to a method for purifying SP-D antibody. The method of invention VIII is not required for the method of purifying SP-D antibodies of invention X, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800~~1630~~

Dr. D. Crouch
October 3, 2000